IN THE MISSOURI SUPREME COURT

NO. SC86104

UNITED PHARMACAL COMPANY OF MISSOURI, INC.,

Respondent,

VS.

MISSOURI BOARD OF PHARMACY,

Appellant.

APPEAL FROM THE BUCHANAN COUNTY CIRCUIT COURT
FIFTH JUDICIAL CIRCUIT
THE HONORABLE WELDON C. JUDAH

RESPONDENT'S SUBSTITUTE BRIEF

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Respondent United Pharmacal Company of Missouri, Inc. adopts Appellant's Jurisdictional Statement.

STATEMENT OF FACTS

I. INTRODUCTION

This appeal arises from the entry of summary judgment in favor of Plaintiff-Respondent United Pharmacal Company of Missouri, Inc. ("UPCO") on its declaratory judgment action against Defendant-Appellant Missouri Board of Pharmacy (the "Board"). In its declaratory judgment action, UPCO sought a declaration that the Board promulgated a rule in excess of the authority granted by the legislature, and that the rule was promulgated without following the applicable rule-making procedures of the Missouri Administrative Procedures Act ("MAPA"). L.F. 13-14. The rule at issue is the Board's recently adopted policy that companies like UPCO must be licensed as a pharmacy or employ a licensed pharmacist in order to sell federal veterinary legend drugs[1] to consumers for animal use pursuant to a veterinarian's prescription. *See* L.F. 11-12, ¶¶ 15-22. This policy, adopted in 1998, reversed the Board's prior policy that such conduct did not violate the Pharmacy

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[1] A "federal veterinary legend drug" is a prescription drug that is approved by the FDA for use in animals. L.F. 44, ¶ 6; L.F. 206, ¶ 6. The federal veterinary legend states "Federal law restricts this drug to use by or on the order of a licensed veterinarian," but does not state who can *sell* a veterinary legend drug. L.F. 44, ¶ 7; L.F. 206, ¶ 7.

Practices Act, RSMo Chapter 338. Since 2001, the Board's new rule has been reflected on the Board's website as "Frequently Asked Question No. 8" ("FAQ #8"). L.F. 12, ¶ 24.

All three points presented by the Board for review by this Court relate to whether the trial court's exercise of jurisdiction and venue were proper under the Missouri Administrative Procedures Act (RSMo Chapter 536). The primary issue is whether the Board's change of policy and/or FAQ #8 is a "rule" -- an issue directly presented in Appellant's Point II and pertinent to Appellant's Point I (whether venue was proper under the special venue provisions of RSMo §536.050 applicable to "rules"). The Board's third Point is that the trial court lacked jurisdiction to enter a declaratory judgment because it did not resolve a "presently existing controversy." Notably, the Board does not challenge as erroneous the trial court's ultimate rulings on the merits of UPCO's declaratory judgment action, *i.e.*, that Chapter 338 does not grant the Board the power to regulate the sale of drugs other than to "patients (humans) upon the prescription by physicians and other human health-care professionals," and that the Board engaged in improper rule-making rendering the rule "unlawful and void." L.F. 219.

II. BACKGROUND

The facts are largely undisputed. With very few exceptions, the Board admitted the facts set forth in UPCO's cross-summary judgment motion. *See* L.F. 206. UPCO

is a retail store that sells animal feeds and products. L.F. 11, ¶ 14. For approximately 20 years, it has sold drugs bearing federal veterinary legends to animal owners pursuant to veterinary prescriptions. *Id.* The Pharmacy Board has monitored UPCO's operations the past twenty years and was aware of such sales. *Id*. ¶¶ 15-16. In fact, in 1994, the Board specifically investigated UPCO based on a complaint by a veterinarian that UPCO was selling veterinary legend drugs directly to consumers without being licensed as a pharmacy. L.F. 44, ¶ 5; L.F. 206, ¶ 5. At that time, the Board determined that UPCO was not violating the Pharmacy Practices Act. L.F. 44, ¶ 8; L.F. 206, ¶ 8.

In 1997, the Board again investigated UPCO for issues relating to the sale of human legend drugs, as well as licensure issues. L.F. 44, ¶ 9; L.F. 206, ¶ 9. Again, the Board took no action against UPCO for selling animal legend drugs without a pharmacy license. L.F. 44, ¶ 11; L.F. 206, ¶ 11.

In 2000, Pharmacy Board Inspector Tom Glenski – on his own initiative, without the direction of the Pharmacy Board – began a third investigation of UPCO. L.F. 48, ¶ 36; L.F. 208, ¶ 36. Inspector Glenski directed Inspector Raya Morris to place an order with UPCO for a veterinary legend product. L.F. 120; L.F. 47, ¶ 26; L.F. 207, ¶ 26. On November 11, 2000, Inspector Morris presented to UPCO a veterinarian's prescription for federal veterinary legend drugs, and UPCO filled that prescription. L.F. 120; L.F. 47, ¶ 24; L.F. 207, ¶ 24; L.F. 123. Inspector Glenski

submitted his Investigation Report on May 16, 2001, in which he concluded that "UPCO is practicing pharmacy without a license by selling veterinary legend drugs to the public based on veterinarian orders." L.F. 121.

On June 21, 2001, Kevin Kinkade, Executive Director of the Pharmacy Board, issued a "Cease and Desist Warning" letter to UPCO stating that it was in violation of §§ 338.010.1, 338.220 and 338.195 of the Pharmacy Practices Act. L.F. 47-48, ¶¶ 29-30; L.F. 207, ¶¶ 29-30 (A4). In its letter, the Board ordered UPCO to cease selling animal legend drugs directly to consumers without being licensed as a pharmacy. L.F. 48, ¶ 32; L.F. 207, ¶ 32; L.F. 125 (A4). The Board admitted that it did not follow the rulemaking procedures of the MAPA before sending the Cease and Desist Warning Letter. L.F. 132.

At the time the Cease and Desist Warning Letter was issued, as now, Section 338.010.1 defined the "practice of pharmacy" as follows:

> The "**practice of pharmacy**" shall mean the interpretation and evaluation of prescription orders; the compounding, dispensing and labeling of drugs and devices pursuant to prescription orders; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with patients and other health care practitioners about the safe and effective use of

> drugs and devices; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his duties. This assistance in no way is intended to relieve the pharmacist from his responsibilities for compliance with this chapter and he will be responsible for the actions of the auxiliary personnel acting in his assistance. This chapter shall also not be construed to prohibit or interfere with any legally registered practitioner of medicine, dentistry, podiatry, or veterinary medicine, or the practice of optometry in accordance with and as provided in sections 195.070 and 336.220, RSMo, in the compounding or dispensing of his own prescriptions.

RSMo § 338.010.1 (2000) (A8).

Section 338.220 declared it unlawful for persons to operate or maintain a "pharmacy" without a license:

> It shall be unlawful for any person, copartnership, association, corporation or any other business entity to open, establish, operate or

maintain any pharmacy, as defined by statute without first obtaining a permit or license to do so from the Missouri board of pharmacy.

RSMo § 338.220 (2000) (A14). That statute also established nine classes of pharmacy permits or licenses that may be issued:

(1) Class A: Community/ambulatory;

(2) Class B: Hospital outpatient pharmacy;

(3) Class C: Long-term care;

(4) Class D: Home health care.

(5) Class E: Radio pharmaceutical;

(6) Class F: Renal dialysis;

(7) Class G: Medical gas;

(8) Class H: Sterile product compounding;

(9) Class I: Consultant services.

Id. A tenth classification of license ("Class J: Shared Services") was added in an August 2001 amendment to § 338.220. *See* RSMo § 338.220 (Cum. Supp. 2003) (A15).

Section 338.195 makes it a class C felony for a person to violate Sections 338.010 through 338.315:

> Any person, who is not licensed under this chapter, who violates any provision of sections 338.010 to 338.315 shall, upon conviction, be adjudged guilty of a class C felony.

RSMo § 338.195 (2000) (A10).

Although not referenced in the Cease and Desist Warning Letter, of importance to this case is § 338.210, which defines "pharmacy." At the time the Cease and Desist Warning Letter was issued to UPCO, § 338.210 defined "pharmacy" as follows:

> As used in sections 338.210 to 338.300 "**pharmacy"** shall mean any pharmacy, drug, chemical store, or apothecary shop, conducted for the purpose of compounding, and dispensing or retailing of any drug, medicine, chemical or poison when used in the compounding of a physician's prescription.

RSMo § 338.210 (2000) (A11).

The statutory definition of "pharmacy" was broadened by the August 2001 amendment to § 338.210. That statute, as amended, provides, in pertinent part:

> 1. Pharmacy refers to any location where the practice of pharmacy occurs or such activities are offered or provided by a pharmacist or another acting under the supervision and authority of a pharmacist, including every premises or other place:
>
> (1) Where the practice of pharmacy is offered or conducted;

(2) Where drugs, chemicals, medicines, prescriptions, or poisons are compounded, prepared, dispensed or sold or offered for sale at retail;

(3) Where the words "pharmacist", "apothecary", "drugstore", "drugs", and any other symbols, words or phrases of similar meaning or understanding are used in any form to advertise retail products or services;

(4) Where patient records or other information is maintained for the purpose of engaging or offering to engage in the practice of pharmacy or to comply with any relevant laws regulating the acquisition, possession, handling, transfer, sale, or destruction of drugs, chemicals, medicines, prescriptions or poisons.

RSMo § 338.210 (Cum. Supp. 2003) (A11).

The Pharmacy Board has not commenced any administrative proceeding against UPCO. L.F. 49, ¶ 40; L.F. 208 ¶ 40. Nor can it commence such a proceeding because, as the Board admitted, it has no authority to commence an administrative proceeding against an unlicensed business. L.F. 49, ¶ 41; L.F. 208, ¶ 41.

Before 1998, the Board's policy was that the Pharmacy Practices Act did not prohibit a business from selling federal veterinary legend drugs to consumers pursuant to veterinary prescriptions without a pharmacy license or though a licensed

pharmacist. This policy is evidenced by the fact that the Board twice investigated UPCO for such conduct, as discussed above, and determined that no violation existed. In addition, Lonnie Calhoun, manager of West Plains Veterinary Supply, Inc., testified that the Board had been aware for 15 years that West Plains was engaging in the same conduct as UPCO, but no action was taken against it until July 26, 2001. L.F. 146-47. Further, in March 1994, the Board told a licensed drug distributor that it could sell veterinary legend products to customers with a veterinarian prescription. L.F. 151, ¶ 2.[2] Still further, in a verified Petition filed by the Pharmacy Board in the case styled, *Missouri Board of Pharmacy v. Chariton Vet Supply, Inc.*, in the Circuit Court of Randolph County, Missouri, filed August 21, 2000, the Board stated:

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[2] In an August 16, 2002, letter to UPCO's counsel, the Board listed seven other times the Board has handled an incident involving the sale of veterinary drugs. L.F. 151. Of those incidents, there was only one in which the Board sent a cease and desist letter to an entity selling veterinary drugs before the Board's 1998 change in policy. That case is inapposite, however, because it involved a "licensed drug distributor" who voluntarily complied with the Board's cease and desist warning, and the letter does not indicate that the distributor was dispensing drugs pursuant to a veterinarian prescription. *See* L.F. 151, ¶ 1.

> 15. For purposes of this action, the Board maintains it has jurisdiction over dispensing of human legend drugs, but it does not assert similar authority for dispensing of veterinary legend drugs.

L.F. 79, ¶ 15; L.F. 45, ¶ 14; L.F. 207, ¶ 14.

The Pharmacy Board changed its policy in 1998 beginning with the *Chariton* case. L.F. 45, ¶¶ 12-13; L.F. 206-07, ¶¶ 12-13; L.F. 65, at 37:17-39:16. In October 1998, the Board issued a Cease and Desist Warning Letter to Chariton alleging, in part, that Chariton was dispensing animal legend prescription drugs to consumers without being licensed as a pharmacy. L.F. 45, ¶¶ 12-13; L.F. 206-07, ¶¶ 12-13; L.F. 90. As alluded to above, in August 2001, the Board filed suit against Chariton in the Circuit Court of Randolph County, Missouri, seeking a preliminary and permanent injunction, pursuant to RSMo § 338.365.[3] L.F. 75; L.F. 45, ¶ 12; L.F. 206, ¶ 12.

In settlement of that lawsuit, the Board and Chariton entered into a Consent Agreement wherein Chariton agreed, in part, to cease the sale of animal legend drugs to consumers without being licensed as a pharmacy. L.F. 45, ¶ 15; L.F. 207, ¶ 15. Pursuant to the Consent Agreement, the Randolph County Court entered an order

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[3] RSMo § 338.365 (2000) authorizes the Board of Pharmacy to seek an injunction or restraining order to enjoin a *wholesale* drug distributor from, among other things, engaging in the practice of pharmacy without a license. RSMo § 338.365.1(1).

granting a permanent injunction against Chariton. L.F. 46, ¶ 16; L.F. 207, ¶ 16. This order was not a determination by the court that Chariton had violated any licensure laws, but rather a voluntary agreement between the parties. L.F. 46, ¶ 18; L.F. 207, ¶ 18.

The lawsuit against Chariton in 2001 was the "first formal action" taken by the Pharmacy Board to prohibit businesses without a pharmacy license or pharmacist from selling animal legend drugs directly to consumers. L.F. 65, at 38:12-17. Prior to 2001, the Board never sought to enjoin any entity that did not have a licensed pharmacist from selling veterinary legend drugs to consumers pursuant to a veterinarian's prescription. L.F. 129. Kevin Kinkade, Executive Director of the Pharmacy Board, testified as follows regarding the change in Board policy:

> Q. And again the question is do you know why the Board decided to initiate court action for these types of – or this type of conduct?
>
> A. Based on the information that the Board was provided on the first entity the Board made a decision after discussing the information that it had to pursue such an action.
>
> Q. Certainly you would agree that prior to that time the Board was not enforcing or initiating any actions against entities for selling animal legend drugs to consumers, is that a fair statement?

A. To my recollection the Board had never initiated any type of action.

Q: Do you have any knowledge of why the Board decided to start doing this? Was it a change in the board members, was there a change in a law, a change in a rule, what was it?

A: The only information I have is that they reviewed information in this case, discussed the case, and I'm talking about the first case that was sent for formal action, and they made a determination at that point by motion and vote to follow that action. I don't have any information other than that.

L.F. 65, 38:18-39:16.

Counsel for the Board expounded on Mr. Kinkade's testimony, explaining at the hearing on the parties' cross motions for summary judgment that the Board's change of policy was due to a new and different interpretation of the law:

MR. HYLTON: Yes. The Board got good counsel finally and they decided to interpret the statute the way it says. . . .

Tr. 31.

The Pharmacy Board relied on the *Chariton* case as the basis for its cease and desist warnings to UPCO and others[4] for selling animal legend drugs. As stated in Inspector Glenski's May 16, 2001, Investigation Report:

> Based on a recent court interpretation that the sale of legend veterinary drugs is the practice of pharmacy . . . .

L.F. 120. Inspector Glenski further stated in his Investigation Report that he advised Frank Evans, owner of UPCO, on April 24, 2001:

> [T]hat based on a recent court case the Board believes that the sell [sic] of veterinary legend drugs based on a veterinarian's order would be considered the practice of pharmacy and the product could only be dispensed by a pharmacist in a pharmacy or the prescribing veterinarian.

L.F. 47, ¶ 28; L.F. 207, ¶ 28.

Inspector Glenski's references to a "recent court case" and "recent court interpretation" were to *Chariton*. L.F. 47, ¶ 27; L.F. 207, ¶ 27; L.F. 75. The Board relied on *Chariton* even though it knew that the *Chariton* court's order was based on

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[4] In the observation report with respect to West Plains Veterinary Supply, Inc., the Board stated: "A recent court case held that only dispensing veterinarians or pharmacies may dispense veterinary legend drug items to "end users." L.F. 149.

a voluntary settlement and not the court's own interpretation of "the practice of pharmacy." *See* L.F. 46, ¶ 18; L.F. 207, ¶ 18.

In 2001, the following question and answer were posted on the Pharmacy Board's public information website:

> 8. Does an entity have to be licensed as a pharmacy to sell veterinary legend drugs to the consumer/owner of the animal(s)?
>
> Yes. Veterinary legend drugs may only be sold based on the order/prescription of a veterinarian. An entity may not sell veterinary legend drugs directly to the consumer (owner of animal) based on a prescription without being licensed as a pharmacy. . . .

(hereinafter "FAQ #8"). L.F. 118; L.F. 51, ¶¶ 54-55; L.F. 209, ¶ 54-55 (A7).

FAQ #8 was drafted by Sharon Roberts, a Pharmacy Board staff member. L.F. 52, ¶ 60; L.F. 209 ¶ 60. The Board did not approve FAQ #8 before it was posted on the Board's website. L.F. 52, ¶ 59; L.F. 209, ¶ 59. Nor did the Board follow the Missouri Administrative Procedures Act rulemaking procedures before posting FAQ #8. L.F. 52, ¶ 57; L.F. 209, ¶ 57; L.F. 132. Rather, as the Board admitted, FAQ #8 reflects the Pharmacy Board staff's interpretation of §§ 338.010 and 338.210, as those statutes do not expressly state that an entity must be licensed as a pharmacy to sell federal veterinary legend drugs to consumers:

Q: And again anywhere in 338.210 which is pharmacy defined does that statute contain the language contained in frequently asked question and answer number eight?

A: It does not.

Q: And was that then the staff's interpretation of that statute?

A: Yes.

L.F. 69, at 77:12-19; *see also* L.F. 52, ¶¶ 62-65; L.F. 209, ¶¶ 62-65; L.F. 131, ¶¶ 13-14.

The Board admitted that FAQ #8 is not an interpretation issued with respect to a specific set of facts and intended to apply only to that set of facts. L.F. 52, ¶ 56; L.F. 209, ¶ 56. In addition to issuing cease and desist warnings to Chariton and West Plains (as discussed above), the Pharmacy Board stated to at least eleven entities that in order to sell federal veterinary legend drugs directly to consumers within the state of Missouri, they must establish approved pharmacies and/or employ a pharmacist to effectuate those sales. L.F. 49-50, ¶ 44; L.F. 208, ¶ 44. The Pharmacy Board believes that all entities such as UPCO have an obligation to comply with the statement contained in FAQ #8 in order to be in compliance with the statutes. L.F. 69-70, 80:21-21.

III. PROCEDURAL HISTORY

On January 11, 2002, UPCO filed a Petition in the Circuit Court of Buchanan County, Missouri – the county of its residence -- seeking a declaration that the Board promulgated a rule in excess of the authority granted by the legislature, and that the rule was promulgated without following proper rule-making procedures. L.F. 8.

On February 11, 2004, the Board filed its Motion to Dismiss asserting lack of jurisdiction and venue. L.F. 16. The Board filed an amended motion to dismiss on April 4, 2002, to correct a typographical error in referring to § 536.050. L.F. 18. On May 21, 2002, the trial court ruled that the Board's motion must be treated as one for summary judgment, and requested that the Board file its motion in summary judgment format. L.F. 3. On June 17, 2002, the Board filed its Motion to Dismiss, or in the Alternative, for Summary Determination. L.F. 35.

UPCO filed its cross-motion for summary judgment on August 28, 2002 (L.F. 43), as well as its response to the Board's summary judgment motion. L.F. 174.

Oral argument was held on October 17, 2002. L.F. 6. On November 1, 2002, the trial court granted UPCO's cross-motion for summary judgment and denied the Board's motion for summary determination. L.F. 213. The trial court stated that it "fails to discern any express legislative intent [in Chapter 338] to extend the powers of the Defendant to encompass the regulation of drugs to other than patients (humans) upon the prescription by physicians and other human health-care professionals." L.F.

219. It further ruled that the subject FAQ was a "rule" and was not enacted in compliance with MAPA. *Id.*

The Missouri Court of Appeals for the Western District of Missouri affirmed the judgment of the trial court in an opinion filed April 30, 2004. *United Pharmacal Company of Missouri, Inc. v. Missouri Board of Pharmacy*, 2004 WL 913537 (Mo. App. W.D. 2004). This Court accepted transfer of this case on August 24, 2004.

POINTS RELIED ON

I. Response to Point II -- The trial court did not err in finding that the Pharmacy Board's change in policy, as confirmed on the Board's website in Frequently Asked Question No. 8, is a "rule" because it satisfies the definition of a "rule" as set forth in RSMo § 536.010 and case law in that the Board's reversal of its long standing agency policy to require a pharmacy license for the sale of federal veterinary legend drugs for animal use pursuant to veterinary prescription is a "statement of general applicability that implements, interprets, or prescribes law or policy."

1700 York Assoc. v. Kaskel, 701 N.Y.S.2d 233 (1999)

Ketring v. Sturges, 372 S.W.2d 104 (Mo. 1963)

NME Hosp., Inc. v. Dep't of Social Services, 1992 WL 96022 (Mo. App. W.D. 1992), *aff'd in part, rev'd in part*, 850 S.W.2d 71 (Mo. banc 1993);

State ex rel. Beaufort Transfer Co. v. Public Service Comm'n, 610 S.W.2d 96 (Mo. App. W.D. 1980)

RSMo § 536.010(6), as amended H.B. 978, § A, 92nd Gen. Assem., 2d Reg. Sess. (Mo. 2004)

RSMo § 338.010 (2000)

RSMo § 338.140 (2000)

RSMo § 338.210 (2000)

RSMo § 338.210 (Cum. Supp. 2003)

RSMo § 338.220 (2000)

RSMo § 338.220 (Cum. Supp. 2003)

RSMo § 338.195 (2000)

RSMo § 340.200.28 (2000)

RSMo § 340.216.1 (2000)

II. Response to Point I -- The trial court did not err in finding that venue was proper because RSMo § 536.050 provides that the court in the county of plaintiff's residence has venue over "declaratory judgment actions respecting the validity of rules or threatened application thereof," and includes claims involving the threatened application of a statute where there is no pending or available administrative proceeding, in that UPCO's place of residence is Buchanan County, its action is a declaratory judgment action respecting the validity of and threatened application of a "rule," or, in the alternative, the Board has threatened application of a statute and no administrative action is pending against or available to UPCO.

Braun v. Petty, 129 S.W.3d 449 (Mo. App. E.D. 2004)

Group Health Plan, Inc. v. State Board of Registration for the Healing Arts, 787 S.W.2d 745 (Mo. App. E.D. 1999)

Farm Bureau Town and Country Ins. Co. of Missouri v. Angoff, 909 S.W.2d 348 (Mo. banc 1995)

Levinson v. State of Missouri, 104 S.W.3d 409 (Mo. banc 2003).

RSMo § 536.050 (2000)

III. Response to Point III -- The trial court did not err in declaring UPCO's rights under RSMo Chapter 338 because it resolved a presently existing controversy regarding UPCO's current and prospective entitlement to sell federal veterinary legend drugs in that the trial court construed both the prior and 2001 amended versions of § 338.210.1.

Missouri Soybean Ass'n, Inc. v. Missouri Clean Water Comm'n, 102 S.W.3d 10 (Mo. banc 2003)

State ex rel. Sch. Dist. of City of Independence v. Jones, 653 S.W.2d 178 (Mo banc 1983)

RSMo § 338.195 (2000)

RSMo § 338.210 (2000)

RSMo § 338.210 (Cum. Supp. 2003)

ARGUMENT

I. Response to Point II -- The trial court did not err in finding that the Pharmacy Board's change in policy, as confirmed on the Board's website in Frequently Asked Question No. 8, is a "rule" because it satisfies the definition of a "rule" as set forth in RSMo § 536.010 and case law in that the Board's reversal of its long standing agency policy to require a pharmacy license for the sale of federal veterinary legend drugs for animal use pursuant to veterinary prescription is a "statement of general applicability that implements, interprets, or prescribes law or policy."

A. Standard of Review

Review of a summary judgment is essentially de novo. *ITT Commercial Finance Corp. v. Mid-America Marine Supply Corp*., 854 S.W.2d 371, 376 (Mo. banc 1993).

B. Argument

UPCO responds to the Board's Point II first because this Court must first decide whether we are dealing with a "rule" before it can consider the issue presented in the Board's Point I – whether the special venue provision of RSMo § 536.050 for actions involving the validity or threatened application of a "rule" applies.

UPCO could not disagree more strongly with the Board's characterization of the issue in this case – that UPCO's "entire case is based on the premise that non-

binding, interpretative statements placed by staff on a Board website in an effort to help Missouri citizens, constitute rules." Appellant's Substitute Brief, p. 18.

As evident from a plain reading of UPCO's Petition (L.F. 8), and clearly and unambiguously reiterated in its cross-motion for summary judgment (L.F. 158) and appellate brief in the Missouri Court of Appeals, UPCO's case is premised on the Board's reversal, in 1998, of its long-standing policy that a licensed pharmacy or pharmacist is required in order to dispense veterinary legend drugs to consumers/animal owners pursuant to veterinary prescriptions. In 2001, that change in policy was published in written form via FAQ #8. L.F. 118. In other words, ***the challenged "rule" is the Board's change in policy; FAQ #8 is merely confirmation of the Board's change in policy***. A change in long-standing agency policy constitutes a "rule." *See State ex rel. Beaufort Transfer Co. v. Public Service Comm'n*, 610 S.W.2d 96, 97-100 (Mo. App. W.D. 1980) (Before 1976, Public Service Commission designated common carriers' routes by Commission report and order; in 1976, the PSC staff began using a formula to determine each carrier's route; court held that the use of the formula was a rule). Only in the alternative does UPCO contend that FAQ #8 is itself a "rule."

1. The Pharmacy Board's Change in Policy is a "Rule"

The Missouri Administrative Procedures Act defines a "rule" as a "statement of general applicability that implements, interprets, or prescribes law or policy, or that

describes the organization, procedure or practice requirements of an agency." RSMo § 536.010(6).[5] (A24). Section 536.010(6) goes on to state that a "rule" includes the amendment or repeal of an existing rule . . . ." *Id.* The section then enumerates thirteen types of agency action that do not constitute "rules." Among them, a "rule" does not include "an interpretation issued by an agency with respect to a specific set of facts and intended to apply only that specific set of facts," which is essentially a restatement of the fact that a "rule" must be a statement of "general applicability." § 536.010(6)(b). (A24).

Although not every generally applicable agency statement is a "rule," *Baugus v. Director of Revenue*, 878 S.W.2d 39, 42 (Mo. banc 1994), this one clearly is. "Implicit in the concept of the word "rule" is that the agency declaration has a potential, however, slight, of impacting the substantive or procedural rights of some member of the public. Rulemaking, by its nature, involves an agency statement that affects the rights of individuals in the abstract." *Id.* The Board's change in policy falls squarely within the definition of a "rule" both in § 536.010(6) and *Baugus.*

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[5] This section was formerly § 536.010(4). A 2004 amendment to § 536.010 changed the numbering but not the definition of a "rule." *See* H.B. 978, § A, 92nd Gen. Assem., 2d Reg. Sess. (Mo. 2004).

The Board contends that what is at issue in this case is the threatened application of a statute – not a "rule" -- because the Board's cease and desist warning to UPCO referenced only violations of "statutes" (Sections 338.010.1, 338.220 and 338.195 of the Pharmacy Practices Act). However, nothing in these sections -- or in Chapter 338 generally – expressly empowers the Pharmacy Board to regulate the sale of drugs for *animal* use pursuant to *veterinary* prescriptions, as opposed to sales of drugs for *human* use pursuant to *physician* prescriptions, as the Board has admitted. L.F. 69, at 77:12-19; *see also* L.F. 131, ¶¶ 13-14. Indeed, §§ 338.010 and 338.210 refer to "patients" and "physicians," which, as the trial court ruled, evidences a legislative intent that the Board regulate only the sale of drugs for human use. L.F. 219; see A8; A11; A12.

Before 1998, the Pharmacy Board consistently maintained the policy that a company was not required to have a pharmacy license or hire a licensed pharmacist to sell veterinary legend drugs to consumers/animal owners. That former policy is evidenced by the fact that the Pharmacy Board has known for at least a decade that UPCO and other businesses in Missouri routinely sold federal veterinary legend drugs to consumers pursuant to veterinary prescriptions without a licensed pharmacist on the premises. *See* L.F. 11, ¶ 15-16 (the Board has monitored UPCO's operations the past twenty years); L.F. 146-47 (West Plains Veterinary Supply, Inc. engaged in same conduct as UPCO for 15 years but no action taken until July 26, 2001); L.F. 65, 38:18-

39:16 (the suit against Chariton Vet Supply, Inc. was the first time the Board had ever initiated any action against an entity for selling animal legend drugs to consumers). Indeed, the Board twice determined – in 1994 and 1997 – that UPCO was not in violation of the Pharmacy Practices Act licensing requirements for dispensing veterinary legend drugs to consumers. *See* L.F. 44-45, ¶ 5, 8, 9, 11; L.F. 206, ¶ 5, 8, 9, 11.

Moreover, the Board unequivocally admitted in *Chariton* that "[f]or purposes of this action, the Board maintains it has jurisdiction over the dispensing of human legend drugs, *but it does not assert similar authority for dispensing of veterinary legend drugs.*" L.F. 79, ¶ 15; L.F. 45, ¶ 14; L.F. 207, ¶ 14 (emphasis added).

In 1998, the Pharmacy Board reversed its policy when it began interpreting Chapter 338 as prohibiting such sales. The *Chariton* case marked the first time that the Board had pursued a company for selling veterinary legend drugs to consumers without a license. L.F. 65, 37:17-39:16. The Board issued a cease and desist letter to Chariton in October 1998. L.F. 45, ¶¶ 12-13; L.F. 206-07, ¶¶ 12-13. After that date, the Board also took action against West Plains Veterinary Supply, Inc. on July 26, 2001 (L.F. 146-47), and stated to at least eleven entities that they must have a pharmacy license in order to sell federal veterinary legend drugs directly to consumers. L.F. 49-50, ¶ 44; L.F. 208, ¶ 44; *see also* L.F. 151, ¶¶ 2, 5, 7.

In 2001, the Board's new policy was placed in written form on its website as FAQ #8:

> 8. Does an entity have to be licensed as a pharmacy to sell veterinary legend drugs to the consumer/owner of the animal(s)?
>
> Yes. Veterinary legend drugs may only be sold based on the order/prescription of a veterinarian. An entity may not sell veterinary legend drugs directly to the consumer (owner of animal) based on a prescription without being licensed as a pharmacy. . . .

L.F. 118 (A7).

The Board's reversal of its long-standing policy constitutes a "rule," and FAQ #8 is an embodiment of that rule. As stated above, a change in long-standing agency policy constitutes a "rule." *See Beaufort*, 610 S.W.2d at 97-100. *Beaufort* involved certain actions of the Public Service Commission (PSC). The PSC controlled the routes for common carriers by issuing orders granting a carrier route authority in a particular "contiguous trade territory." *Id.* at 98. "Contiguous trade territory" was never defined by the PCS, but rather each carrier construed that term "depending on local conditions and custom and usage." *Id.* This lack of definition presented a problem when, in 1976, the PCS decided to issue a "Certificate of Convenience and Necessity" to each carrier describing its current routes. *Id.* As a result, the PSC staff developed a formula – based on population and mileage – that would be used to define

each carrier's "contiguous trade territory." *Id.* The Commission contended that it had not adopted the formula and therefore no rule was made, but the PSC's staff used the formula to define a carrier's territory, altering the territory from that which the carrier had served for decades. *Id.* at 99.

The PSC argued that the definition of the carrier's territory was simply a clarification and interpretation of previously issued orders. *Id.* at 99. The court, however, held that the formula for re-defining trade territory "amounted to a statement of general applicability and, hence, a rule within the definition of § 536.010, RSMo 1978, and that the order was invalid because required rule making procedures had not been observed." *Id.* at 100.

Similarly, the Board's newly developed policy that veterinary drugs may only be sold to consumers by licensed pharmacies or pharmacists is a statement of general applicability. The policy was not made "with respect to a specific set of facts and intended to apply only that specific set of facts." *See* RSMo § 536.010(6)(b) (A24); L.F. 130, ¶ 12. Rather, it applies to all persons who dispense veterinary drugs to consumers, as evidenced by the fact that the Board pursued not only UPCO for such conduct, but also Chariton Vet Supply, Inc. and West Plains Veterinary Supply, Inc. *See* L.F. 45, ¶¶ 12-13; L.F. 206-07, ¶¶ 12-13; L.F. 146-47. In addition, the Board warned at least eleven other entities that they must have a pharmacy license in order

to sell federal veterinary legend drugs to consumers in this State. L.F. 49-50, ¶ 44; L.F. 208, ¶ 44.

Because Chapter 338 does not expressly authorize the Board to regulate the sale of veterinary drugs, the Board's policy change "implements, interprets or prescribes law or policy." Thus, it is a "rule" under § 536.010(6) (A24). The fact that it was, from 1998 until 2001, an unwritten policy except perhaps in the Board's own internal records does not change this result. *See Beaufort*, 610 S.W.2d at 99 (staff recommended and applied formula, but PSC denied that it ever adopted the formula); *School Board of Broward County v. Bennett*, 771 So.2d 1270 (Fla. App. 2000) (holding that an unwritten policy that allowed teachers aides to perform catheterizations on students if the aides had received training to do so was a rule).

2. In the Alternative, FAQ #8 is a Rule

Even if the Board's unwritten policy that existed since 1998 does not constitute a "rule," the embodiment of that policy in FAQ #8 certainly does. Numerous decisions in this and other jurisdictions establish that a statement of generally applicable agency policy contained in agency materials other than official agency regulations can constitute a "rule:"

- In *Missouri State Division of Family Services v. Barclay*, 705 S.W.2d 518 (Mo. App. W.D. 1986), the court held that a statement contained in DFS' Income Maintenance Manual (IMM) was a rule. The IMM is a "voluminous

compilation of materials and guidelines used by DFS to determine the amount of a Medicaid recipient's income that must be paid to her nursing home. *Id.* at 520-21. The court held that "[t]he method to determine a recipient's allocation of income is a rule within this definition as it 'substantially affects the legal rights of' persons who seek financial aid through the state's Medicaid program." *Id.* at 521. Because the rule was never published or filed as a rule, it was unenforceable. *Id.*

- In *State v. Peters*, 729 S.W.2d 243 (Mo. App. S.D. 1987), the Department of Health approved methods utilized in state laboratories for determining blood alcohol from blood samples. The court held that the Department attempted to implement law as well as to prescribe a policy of the Department, and that therefore the department was required to comply with statutory publication and filing procedures for adopting rules. *Id.* at 243.
- In *NME Hospitals, Inc. v. Department of Social Services*, 1992 WL 96022 (Mo. App. W.D. 1992), *aff'd in part, rev'd in part*, 850 S.W.2d 71 (Mo. banc 1993), the court held that a statement contained in a Medicaid Bulletin was a rule. In a Medicaid Bulletin, the Department of Social Services announced that it would not reimburse Medicaid providers for any psychiatric services provided, except for electroshock therapy. *Id.* at *1. The court held that this statement was a "statement of general applicability that prescribes policy." *Id.* at *2. Since the

rule was not made in accordance with the rulemaking procedure, it was void. *Id.*

- In *Tonnar v. Missouri State Highway and Transportation Commission*, 640 S.W.2d 527 (Mo. App. W.D. 1982), the court held that a statement contained in the Commission's Right-of-Way Manual, which determined who was entitled to relocation assistance, was a rule. The court held:

  > The effect of the Right-of-Way Manual is to declare the policy of the Commission in respect to certain compensation and relocation payments and to set practices and procedures governing the rights of the public in these areas. The contents of the manual are therefore rules within the definition of § 536.010, R.S.Mo. 1978 . . . .

  Id. at 531.

- In *Kansas Association of Private Investigators v. Mulvihill,* 35 S.W.3d 425 (Mo. App. W.D. 2000), the court held that a new schedule of license fees posted at the Board of Police Commissioner's office constituted a rule. *Id.* at 430.

- In *Asmussen v. Commissioner, New Hampshire, Department of Safety*, 766 A.2d 678 (N.H. 2000), the court held that directives issued to administrative law judges instructing them to admit hearsay evidence were rules.

FAQ #8 declares the policy of the Pharmacy Board. The Board admitted that the statement in FAQ # 8 is not a statement that only applies to a specific set of facts, but rather that it is generally applicable. L.F. 52, ¶ 56; L.F. 209, ¶ 56. In fact, it admitted that UPCO and others must comply with the statement contained in FAQ # 8. L.F. 53, ¶¶ 66, 67; L.F. 210 ¶¶ 66, 67. These admissions place the Board's policy as embodied in FAQ #8 squarely within the definition of a "rule." To paraphrase the definition of a "rule," the Board's policy as reflected in FAQ # 8 is a "statement" that is "generally applicable" that "interprets" law or policy, i.e., Chapter 338. *See* RSMo § 536.010(6) (A24).

In contending that FAQ #8 is not a rule, the Board relies on three cases: *Baugus*, 878 S.W.2d 39; *Missouri Soybean Association v. Missouri Clean WaterCommission*, 102 S.W.3d 10 (Mo. banc 2003), and *Missouri National Education Association v. Missouri State Bd. of Educ.*, 34 S.W.3d 266 (Mo. App. W.D. 2001). Although discussed in Point I rather than in its Point II, the Board additionally relies on *Golden Rule Insurance Co. v. Missouri Department of Insurance*, 56 S.W.3d 471, 474 (Mo. App. W.D. 2001), in arguing that FAQ #8 is not a rule. None of these cases support the Board's position.

Baugus is cited by the Board for the proposition that not every generally applicable statement is a "rule." As mentioned above, *Baugus* stated that a rule must have the "potential, however, slight, of impacting the substantive or procedural rights

of some member of the public." *Baugus*, 878 S.W.2d at 42. In that case, a new Senate bill provided that when a vehicle had previously been issued a "salvage" title, all subsequent certificates of title on that vehicle must likewise contain the designation of "salvage." The director of revenue announced that she would affix the label "prior salvage" on all certificates of title issued subsequently to the original salvage title. The plaintiffs objected that this was rule-making without the necessary rule-making procedure. This Court disagreed, stating that insertion of the word "prior" did not "substantially affect the legal rights any party." *Id.* at 42.

In contrast, the rule at issue in this case *does* substantially affect UPCO's substantive legal rights. It prohibits UPCO from engaging in the same conduct that it had engaged in for more than a decade – with the Board's oversight and approval – and subjects UPCO to criminal prosecution. *See* RSMo § 338.195 (2000) (A10).

The challenged "rule" in *Missouri Soybean* suffered from the same problem as in *Baugus* – it did not substantially affect the substantive rights of any person. In *Missouri Soybean*, the Missouri Clean Water Commission decided to place the Missouri and Mississippi Rivers on a list of "impaired waters" to be submitted to the EPA for further study. The appellants argued that the list was a "rule" because it might lead to regulation of their properties at some point in the future. *Id.* at 21. This Court held that inclusion of the rivers on the list was not a "rule.

The Court stated that a rule "establishes a standard of conduct that has the force and effect of law." *Missouri Soybean*, 102 S.W.3d at 23. It noted, however, that the list was not used to determine whether or not the appellants violated any "norm embodied in said list." *Id.* It did not command the appellants to do anything or to refrain from doing something. *Id.* It was merely a list of waters as to which further study was warranted. *Id.* at 24. And, importantly, inclusion on the list did not necessarily lead to land-use regulation; the appellants merely "prophesied that . . . future regulations would adversely impact them." *Id.* Thus, any harm that appellants alleged was purely speculative. *Id.*

In contrast, FAQ #8 reflects the Board's policy that UPCO and other similar businesses must immediately cease selling veterinary legend drugs. As such, it exacts a very real and substantial harm to UPCO and other similar businesses. The Board argues that FAQ #8 was meant to be informative and not to impact the rights of any individual; that it does not, in and of itself, have the force and effect of law, and thus is not a rule. *See* Appellant's Substitute Brief, p. 20. The Board argues that FAQ #8, itself, will not be used to measure UPCO's conduct or compel action on its part. *Id.* This argument is at odds with the Board's admission that UPCO and others must comply with the statement contained in FAQ # 8. L.F. 53, ¶¶ 66-67.

As stated in *Missouri Soybean*, "[r]ulemaking 'involves the *formulation of a policy or interpretation* which the agency will apply in the future to all persons

engaged in the regulated activity." *Missouri Soybean*, 102 S.W.3d at 23 (emphasis added) (citations omitted). It "'affects the rights of individuals in the abstract and must be applied in a further proceeding before the legal position of any particular individual will be definitively touched by it.'" *Id.* (citation omitted).

The Board's policy as reflected in FAQ #8 clearly meets these criteria. The Board formulated a policy or interpretation when it reversed its longstanding position that the sale of veterinary prescription drugs did not require a pharmacy license. The newly adopted policy established a standard of conduct applicable to all persons engaged in the sale of veterinary prescription drugs. In other words, the Board's policy/FAQ #8 did not determine that UPCO, specifically, was required to maintain a pharmacy or have a licensed pharmacist to dispense veterinary prescriptions. Rather, the policy is applicable to all persons who dispense drugs pursuant to veterinary prescriptions. Persons who fail to adhere to that policy face criminal felony prosecution. *See* RSMo § 338.195 (2000) (A10). Further, whether UPCO in fact violated this policy is subject to further proceeding. *See Missouri Soybean*, 102 S.W.3d at 23.

The Board's reliance on *Missouri National Education Association v. Missouri State Board of Education.*, 34 S.W.3d 266 (Mo. App. W.D. 2001), is also misplaced. At issue in that case was a set of "Guidelines" that the MNEA argued was used by the State Board of Education in making decisions whether to grant a school district's

request for an exemption under a certain statute. *Id*. at 286-87. Contrary to the MNEA's arguments, however, the "Guidelines" were not actually guidelines used by the State Board in determining whether to grant an exemption. Although titled "Guidelines," it was actually just a report that listed the reasons that the school districts had proffered when requesting exemptions the previous year. *Id*. at 287. The State Board never voted to adopt or utilize the report, nor did they actually use the report in deciding whether to grant or deny a request for exemption. *Id.* Under these facts, this Court ruled that the Guidelines were not "rules." *Id.*

Here, on the other hand, the Board actually adopted a policy (one directly opposed to its former policy), published notice of that policy on its website, and sought to enforce that policy against UPCO and others. Again, the Board admitted that UPCO and others must comply with the statement contained in FAQ # 8. L.F. 53, ¶¶ 66-67.

Golden Rule is also inapposite. There, *Golden Rule* submitted a proposed health insurance rider form to the Department of Insurance for its approval. *Golden Rule*, 56 S.W.3d at 472. The issue was whether the rider form constituted a "managed care plan" or a "health indemnity plan." *Id.* Importantly, both terms are defined by statute. *Id.* Applying the statutory definition, the Department of Insurance determined that Golden Rule's rider form was a managed care plan. *Golden Rule* filed a declaratory judgment action, rather than pursuing its available administrative

remedies. It argued that "the threat to apply the statue is necessarily a threat to apply agency rules promulgated under the statute." *Id.* at 474. The court correctly rejected that argument, stating that "[i]f we accept Golden Rule's argument, every challenge to a statute could be considered an attack on the rules promulgated thereunder." *Id.*

Golden Rule is inapposite first because the agency was merely applying a *statutorily defined* term as written. It did not apply any agency rule to determine whether the rider form fell within the statutory definition was a managed care plan. *Id.* at 474. In contrast, here, Chapter 338 does not expressly include the sale of veterinary drugs to animal owners within its definition of the "practice of pharmacy." The Board had to resort to an internally developed policy to determine whether UPCO's conduct constituted the "practice of pharmacy." As counsel for the Board stated, the policy was made when its counsel interpreted the statute differently than it previously had:

> MR. HYLTON: Yes. The Board got good counsel finally and they decided to interpret the statute the way it says. . . .

Tr. 31.

Second, *Golden Rule* is inapposite because the plaintiff in that case had an administrative proceeding available to it, which it failed to use. In contrast, there is no administrative process that UPCO, as an unlicensed entity, can initiate. Nor, as the Board admitted, can it take any administrative action against UPCO. L.F. 49, ¶ 41;

L.F. 208, ¶ 41. Under these circumstances, a declaratory judgment action under § 536.050 is proper. *See Group Health Plan, Inc. v. State Bd. of Registration for the Healing Arts*, 787 S.W.2d 745, 748 (Mo. App. E.D. 1990) (discussed more fully in the Response to Appellant's Point I, *infra*).

These differences answer the Board's slippery slope argument that if UPCO prevails here every agency interpretation of a statute would be challenged as unlawful rulemaking. *See* Appellant's Substitute Brief, p. 17. Under the facts of this case, the Board is not applying a statutorily defined term, as in *Golden Rule*. Rather, it engrafted an entirely new field into the statutory definition of "practice of pharmacy" – proscribing conduct that the Board had previously determined did not violate Chapter 338. UPCO has no administrative remedy available to challenge the Board's change in policy.

The Board also suggests that FAQ #8 is not a rule because its staff was merely interpreting a statute. However, staff interpretations of statutory terms are "rules," which must be promulgated with rulemaking procedures. *See Beaufort*, 610 S.W.2d at 96; *Ketring v. Sturges*, 372 S.W.2d 104 (Mo. 1963); and *1700 York Assoc. v. Kaskel*, 701 N.Y.S.2d 233 (1999). In *Beaufort*, as discussed above, the court held that a policy developed by agency staff constituted a rule.

Ketring involved an agency interpretation of a statutory term, "dishonorable conduct in optometric practice." *Ketring*, 372 S.W.2d at 110-111. In that case, the

agency's interpretation had already been promulgated as a rule, but the case is important here because it reflects that other agencies follow rulemaking procedures with respect to their interpretations of statutory terms.

In *Kaskel*, the court held that an agency's policy interpreting a city code was a rule. There, a city code prohibited citizens from keeping animals that are "wild, ferocious, fierce, dangerous or naturally inclined to do harm." *Kaskel*, 701 N.Y.S.2d at 240. The Department of Health established a policy interpreting the code provision to include ferrets. *Id.* The court held that this policy was a "rule." *Id.* "The fact that DOH does not call its policy regarding ferrets a rule . . . does not make the policy any less a rule . . . ." *Id.* at 241. "An agency may not circumvent . . . rulemaking requirements by giving a different label to what is in purpose or effect a rule or amendment to a rule." *Id.*

Under the foregoing facts and case law, there is no question that the Board's policy, as established in 1998 and as reflected in FAQ #8, is a "rule." The cases cited by the Board as requiring a contrary result are inapposite.

3. The Board's Rule is a Substantive (Legislative) Rule

The Court of Appeals *sua sponte* raised the issue of whether the Board's rule is an interpretative or substantive (a/k/a legislative) rule, stating that the term "rule" includes not only "substantive" rules, but also interpretative and procedural rules. Neither of the parties briefed or argued this issue in the courts below. But regardless

of whether the rule is substantive/legislative or interpretative, the trial court's judgment must be affirmed. If it is legislative, then the trial court correctly determined that the rule is void for failure to follow the required rule-making procedures. L.F. 219. If it is interpretative, the trial court correctly determined that there is nothing in Chapter 338 that indicates a legislative intent that the Board regulate the sale of federal veterinary legend drugs to consumers with veterinary prescriptions. L.F. 219.

A legislative rule is one that "'grant[s] rights, impose[s] obligations, or produce[s] other significant effects on private interests . . . or which 'effect[s] a change in existing law or policy.'" *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987) (citations omitted). It is "'based on an agency's power to exercise its judgment as to how best to implement a general statutory mandate.'" *Kelley v. Environmental Protection Agency*, 15 F.3d 1100, 1108 (D.C. Cir. 1994) (citation omitted) (emphasis in original). An interpretative rule, on the other hand, is one "which merely clarify[ies] or explain[s] existing law or regulations." *American Hospital*, 834 F.2d at 1045. "[T]he spectrum between a clearly interpretative rule and a clearly substantive one is a hazy continuum." *Id.* "The line of demarcation between the two types is whether the legislature, in its statutory grant of authority, intended the agency to have broad rule-making power. . . . Those regulations promulgated pursuant

to a statutory grant of authority are considered of the legislative variety . . . ." *Pollock v. Wetterau Food Distribution Group*, 11 S.W.3d 754, 766 (Mo. App. E.D. 1999).

The decision of this Court in *Ketring v. Sturges*, 372 S.W.2d 104 (Mo. 1963), is instructive. In that case, the State Board of Optometry promulgated certain rules defining the term "dishonorable conduct in optometric practice," as used in a statute authorizing the Board to suspend or revoke a license on those grounds. *Id.* at 110-111. The Board sent the plaintiff, a licensed optometrist, a letter warning that his employment of an unlicensed optician to measure and fit contact lenses violated these rules. *Id*. at 106-107. The plaintiff filed a declaratory judgment action against the Board challenging the validity of those rules.

The Court stated, "[i]n a sense, these are interpretative rules. However, in view of the legislature's failure fully to define the term and in view of the authority conferred upon the board, *these rules assume a legislative character*." *Id*. at 111 (emphasis added). The Board was granted the authority "adopt reasonable rules and regulations within the scope and terms of this chapter for the proper administration and enforcement therefore" and "to do all other things necessary to carry out the provisions of this chapter." *Id.* at 108.

In the present case, the Board similarly had a broad, general grant of authority "to adopt such rules and bylaws not inconsistent with the law as may be necessary for the regulation of its proceedings and for the discharge of the duties imposed pursuant

to sections 338.010 to 338.198 . . . ." RSMo § 338.140.1 (2000) (A9). As in *Ketring*, although the Board's rule that a person must be licensed as a pharmacist to sell veterinary drugs for animal use is, in a sense, interpretative of the statutory term, the "practice of pharmacy," given the legislature's failure to state whether the "practice of pharmacy" includes such sales, the Board's interpretation assumes a legislative character. This is especially so in that the rule represents a complete change in policy, substantially and adversely affecting the rights and obligations of businesses engaged in such sales – features that are the hallmarks of a "substantive rule." *See American Hospital*, 834 F.2d at 1045; *Baugus*, 878 S.W.2d at 42; *Beaufort*, 610 S.W.2d at 97-100.

4. The Trial Court Correctly Determined that Chapter 338 Does Not Encompass the Sale of Veterinary Drugs for Animal Use

Even if this Court concludes that the Board's change in policy and/or FAQ #8 are interpretative rules, the trial court's judgment must be affirmed because the court correctly determined that nothing in Chapter 338 evinces a legislative intent to regulate the sale of veterinary drugs for animal use pursuant to a veterinarian's prescription. *See* L.F. 219.

At the time the Cease and Desist Warning Letter was issued, as now, Section 338.010.1 defined the "practice of pharmacy" as follows:

> The "**practice of pharmacy**" shall mean the interpretation and evaluation of prescription orders; the compounding, dispensing and labeling of drugs and devices pursuant to prescription orders; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with *patients* and other health care practitioners about the safe and effective use of drugs and devices; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. . . .

RSMo § 338.010.1 (2000) (emphasis added) (A8).

Section 338.210 defined "pharmacy" as follows:

> As used in sections 338.210 to 338.300 "**pharmacy"** shall mean any pharmacy, drug, chemical store, or apothecary shop, conducted for the purpose of compounding, and dispensing or retailing of any drug, medicine, chemical or poison when used in the compounding of a *physician's* prescription.

RSMo § 338.210 (2000) (emphasis added) (A11).

The statutory definition of "pharmacy" was broadened by the August 2001 amendment to § 338.210. That statute, as amended, provides, in pertinent part:

> 1. Pharmacy refers to any location where the practice of pharmacy occurs or such activities are offered or provided by a pharmacist or another acting under the supervision and authority of a pharmacist, including every premises or other place:
>
> * * *
>
> (4) Where *patient* records or other information is maintained for the purpose of engaging or offering to engage in the practice of pharmacy . . . .

RSMo § 338.210 (Cum. Supp. 2003) (emphasis added) (A12).

The use of the words "physicians" and "patients" in these sections indicates the legislature's intent that the Board of Pharmacy regulate only drugs prescribed by *physicians* for *human* use, not drugs prescribed by *veterinarians* for *animal* use. Further, § 338.220.1 lists the various classes of pharmacy licenses that may be issued. Those ten classes are:

> (1) Class A: Community/ambulatory;
>
> (2) Class B: Hospital outpatient pharmacy;
>
> (3) Class C: Long-term care;
>
> (4) Class D: Home health care.
>
> (5) Class E: Radio pharmaceutical;
>
> (6) Class F: Renal dialysis;

(7) Class G: Medical gas;

(8) Class H: Sterile product compounding;

(9) Class I: Consultant services;

(10) Class J: Shared services.

RSMo § 338.220.1 (Cum. Supp. 2003) (A16).

The sale of veterinary drugs for animal use do not readily fall within any of these classes. Rather, these classes all appear to relate to services provided to *humans.*

Indeed, the sale of veterinary drugs would fall within the purview of the Missouri Veterinary Medical Board, which, pursuant to Chapter 340, licenses and regulates veterinarians. Specifically, Section 340.216.1 states that it is unlawful for a person not licensed as a veterinarian to practice veterinary medicine. RSMo § 340.216.1 (2000) (A22). "Veterinary medicine" is defined in § 340.200.28 as:

> [T]he science of diagnosing, treating, . . . or preventing any animal disease, . . . or other physical or mental condition, including, but not limited, to the *prescription* or administration *of any drug,* . . . on any animal . . . *or to render service* or recommendations *with regard to the any of the procedures in this paragraph.*

RSMo § 340.200.28 (2000) (emphasis added) (A21).

However, § 340.216 goes on to state that:

> [N]othing in sections 340.200 to 340.330 shall be construed as prohibiting:
>
> * * *
>
> (4) Any merchant or manufacturer from selling drugs, medicine, appliances or other products used in the prevention or treatment of animal diseases . . . .

RSMo § 340.216.1(4) (2000) (A22).

As evident by the foregoing, UPCO's conduct more appropriately falls within the jurisdiction of the Missouri Veterinary Medical Board, rather than the Missouri Board of Pharmacy. If the legislature intends the Board of Pharmacy rather than the Veterinary Medical Board to regulate the sale of veterinary drugs to animals pursuant to veterinary prescription, it should amend Chapter 338 to so expressly provide, "so that those who must abide by licensure are clearly and fully aware of what types of conduct and business practices are expected." *United Pharmacal Company of Missouri, Inc. v. Missouri Board of Pharmacy*, 2004 WL 913537, *7 (Mo. App. W.D. 2004), *transfer granted* (Aug. 24, 2004).

II. Response to Point I -- The trial court did not err in finding that venue was proper because RSMo § 536.050 provides that the court in the county of plaintiff's residence has venue over "declaratory judgment actions respecting the validity of rules or threatened application thereof," and includes claims involving the threatened application of a statute where there is no pending or available administrative proceeding, in that UPCO's place of residence is Buchanan County, its action is a declaratory judgment action respecting the validity of and threatened application of a "rule," or, in the alternative, the Board has threatened application of a statute and no administrative action is pending against or available to UPCO.

A. Standard of Review

Review of a summary judgment is essentially de novo. *ITT Commercial Finance Corp. v. Mid-America Marine Supply Corp*., 854 S.W.2d 371, 376 (Mo. banc 1993).

B. Argument

1. UPCO's Action Involves the Validity or Threatened Application of a "Rule" and Therefore the Special Venue Provision of § 536.050 Applies.

The Board argues in Point I that the Buchanan County Circuit Court did not have venue over UPCO's cause of action because RSMo § 536.050 (2000) authorizes

a plaintiff to bring a declaratory judgment action in its county of residence only if its action involves the validity or threatened application of a "rule." Since, the Board argues, its Cease and Desist Warning Letter alleged violation of "statutes" rather than "rules," § 536.050 does not apply and venue is proper only in Cole County, Missouri.

To the contrary, as established in the Response to Point II discussed *supra*, the Board's change in policy and/or FAQ #8 is a "rule." Therefore, UPCO's action *does* involve the validity and threatened application of a "rule" and venue in the Circuit Court of Buchanan County is expressly authorized under RSMo § 536.050.1 (2000). (A27).

2. The Special Venue Provisions of § 536.050 Includes Declaratory Judgment Actions Involving the Threatened Application of a Statute Where There is No Administrative Proceeding Pending or Available.

Even if this action does not involve a "rule," § 536.050 has been construed as including declaratory judgment actions involving the threatened application of a statute where, as here, no administrative proceeding has been commenced or is available. *See Group Health Plan, Inc. v. State Board of Registration for the Healing Arts*, 787 S.W.2d 745, 748 (Mo. App. E.D. 1990); *Farm Bureau Town and Country Ins. Co. of Missouri v. Angoff,* 909 S.W.2d 348 (Mo. banc 1995). Therefore, the special venue provisions of § 536.050 would apply to such actions.

In *Group Health Plan*, the issue was whether the court had subject matter jurisdiction over a declaratory judgment action involving the threatened application of a statute. The defendants argued that the plaintiffs had to first exhaust their administrative remedies before resorting to the courts. *Group Health Plan*, 787 S.W.2d at 748. The plaintiffs responded that the defendants had not yet initiated administrative proceedings nor was there any procedure by which they could bring their action, and therefore a declaratory judgment action was their only recourse. *Id*.

The court agreed with the plaintiffs. It stated:

> In the present case, action by the administrative agency has been threatened but not initiated. The courts have jurisdiction to render declaratory judgments questioning the validity of a rule or the threatened application thereof. *See* Section 536.050.1, RSMo (1986). Certainly, if jurisdiction lies to consider the threatened application of rules, it lies to consider the threatened application of statutes. In the absence of a pending administrative action, the trial court has subject-matter jurisdiction to adjudicate plaintiffs' action.

Group Health Plan, 787 S.W.2d at 749.

Group Health Plan's holding that "a party threatened by agency action may invoke the court's jurisdiction to grant declaratory judgment against the agency"

where no administrative proceeding has been commenced was cited with approval by this Court in *Farm Bureau,* 909 S.W.2d at 354.

The Board here argues that *Group Health Plan* merely authorizes a declaratory judgment action, but that the venue of such action would be in Cole County, which is the proper venue for suits against agencies other than those falling within § 536.050. Importantly, however, the action in *Group Health Plan* was filed in St. Louis County – not Cole County. Thus, venue in St. Louis County must have been premised on § 536.050. If, as the Board here argues, the appellate court did not construe § 536.050 as including the threatened application of a statute, then the St. Louis County circuit court had no venue over the declaratory judgment action in *Group Health Plan*. Therefore, the appellate would have, and should have, affirmed the dismissal of the plaintiffs' lawsuit. *See Auto Owners (Mutual) Ins. Co. v. Sugar Creek Memorial Post No. 3976*, 123 S.W.3d 183 (Mo. App. W.D. 2000 ("We must affirm a trial court's ruling on a summary judgment motion if it can be sustained under any theory, even if the trial court reached the correct result for the wrong reasons."); *Braun v. Petty,* 129 S.W.3d 449 (Mo. App. E.D. 2004) (appellate courts "are concerned with the correctness of the trial court's result – not the reasons advanced by the court to reach that result – and will affirm the judgment if it is cognizable under any theory."). Instead, *Group Health Plan* reversed the trial court's dismissal of the action. The fact that the court did not affirm the trial court's dismissal on the grounds that venue was

lacking supports UPCO's position that *Group Health Plan* stands for the proposition that declaratory judgment actions involving the threatened application of a statute fall within § 536.050.1 and thus the venue provisions of that statute apply to such claims.

Similarly, *Levinson v. State of Missouri,* 104 S.W.3d 409 (Mo. banc 2003), involved a declaratory judgment action challenging validity of statutes and regulations where the plaintiff had no administrative remedy available.[6] That action was brought in the Circuit Court of the City of St. Louis, not Cole County. The Court reversed the

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[6] The plaintiff Levinson was on probation for a felony conviction. *Id.* at 410. His probation officer advised him that continued employment as a bartender violated § 311.060.2(2) and CSR 70-2.140(11). *Id.* at 410-11. Section 311.060.2(2) provided that "a liquor license shall not be denied based solely on the fact that an employee has been convicted of a felony unless the employee engages in the direct retail sale of intoxicating liquors." *Id.* at 411. The court noted that although this statute was inapplicable to Levinson because he was not a liquor licensee, the regulations interpret this statute as prohibiting a licensee from employing anyone convicted of a felony, and thus Levinson could have been criminally liable for aiding and abetting a violation of that section. *Id.* Because Levinson was not a liquor licensee, he obviously had no administrative remedy available in which to challenge the statute or regulations.

trial court's dismissal of the case and remanded it back to that court. Again, if venue had been improper, the Court should have affirmed the dismissal on the grounds on lack of venue.

In this case, the Board has not initiated any administrative proceeding. L.F. 49, ¶ 40; 208, ¶ 40. In fact, it has admitted that it has no authority to initiate an action against UPCO, an unlicensed entity. L.F. 49, ¶ 41; L.F. 208, ¶ 41. Nor is there any administrative remedy that UPCO could pursue to seek relief from the Board's threatened action. Under these facts, UPCO has no recourse except to the court.

If the Board's position were adopted, it would invite agencies to avoid citing agency rules as the basis of threatened or actual administrative action in the hopes of trumping judicial review under § 536.050. Just as "[a]n agency may not circumvent . . . rulemaking requirements by giving a different label to what is in purpose and effect a rule or amendment to a rule," (*see 1700 York Associates v. Kaskel*, 701 N.Y.S.2d 233 (1999)), an agency may not circumvent judicial review by threatening application of a rule under the guise of enforcing a statute.

Further, as a matter of fairness and public policy, a person compelled to seek judicial relief because of threatened agency action should not be compelled to seek such relief in the agency's choice of forum – especially where, as here, the agency is acting in excess of its authority and it does not itself afford him an administrative process in which to seek relief. The legislature presumably fixed venue of

administrative proceedings in Cole County as a matter of expediency and judicial economy because of the number of persons who affirmatively seek relief from an adverse decision in a contested case. Those persons, by seeking a license from a state agency, implicitly agree to the administrative procedures inherent thereto, including venue in Cole County. But the policy reasons underlying that decision are overridden in cases such as this involving an *unlicensed* entity. UPCO is not seeking affirmative relief from an adverse decision in a contested matter. Where, as here, an agency acting in excess of its authority is drawing an unlicensed person into a controversy, the burden on that person should not be compounded by forcing him to fight his battle in the agency's backyard with its attendant additional costs. He should be entitled to defend himself in the forum of his choice (*i.e.*, his county of residence or Cole County).

III. Response to Point III -- The trial court did not err in declaring UPCO's rights under RSMo Chapter 338 because it resolved a presently existing controversy regarding UPCO's current and prospective entitlement to sell federal veterinary legend drugs in that the trial court construed both the prior and 2001 amended versions of § 338.210.1.

A. Standard of Review

Review of a summary judgment is essentially de novo. *ITT Commercial Finance Corp. v. Mid-America Marine Supply Corp.*, 854 S.W.2d 371, 376 (Mo. banc 1993).

B. Argument

The Board argues that the trial court erred because it declared UPCO's rights and obligations under Chapter 338 as it existed at the time the Cease and Desist Warning Letter was issued, rather than under the 2001 amendments to Chapter 338. Thus, the Board argues, the trial court did not resolve a presently existing controversy regarding UPCO's prospective rights, as required for entry of a declaratory judgment. The Board's position is unsupported by the plain language of the judgment, the statements of counsel and the court at oral argument (which focus on the proper issue), and the law, which creates a presumption that the trial court's judgment is correct.

The plaintiff in a declaratory judgment action must demonstrate four elements:

> (1) a justiciable controversy that presents a real, substantial and presently-existing controversy admitting of specific relief, as distinguished from an advisory decree upon a purely hypothetical situation; (2) a plaintiff with a legally protectable interest at stake, "consisting of a pecuniary or person interest directly at issue and subject to immediate or prospective consequential relief;" (3) a controversy ripe for judicial determination; and (4) an inadequate remedy at law.

Missouri Soybean Ass'n, Inc. v. Missouri Clean Water Comm'n, 102 S.W.3d 10, 25 (Mo. banc 2003).

1. A Present Controversy Exists

In Point III, the Board challenges only the "presently-existing controversy" requirement for a declaratory judgment. It argues that the trial court did not resolve a presently existing controversy regarding UPCO's prospective[7] rights and duties in

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[7] As a point of clarification, UPCO disagrees with the Board's tag to the "presently existing controversy" element that a court must adjudicate "prospective" rights and duties. The Board apparently gleaned this "requirement" from *Northgate Apartments, L.P. v. City of North Kansas City*, 45 S.W.3d 475, 479 (Mo. App. W.D. 2001), where the court stated, in discussing the second element of a declaratory

that it construed the parties' rights and obligations under Chapter 338 prior to the 2001 amendment to RSMo § 338.210.1 redefining "pharmacy." Since, the Board argues, the trial court construed only the prior version of Chapter 338, UPCO's action is moot.

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judgment action, that the plaintiff must prove a "legally protected interest consisting of a pecuniary or personal interest directly at issue and subject to *immediate or prospective consequential relief.*" *Id.* at 479 (emphasis added). This element refers to *relief* – not *rights.* In other words, the inquiry is whether the court could grant some form of relief that would terminate the controversy. *See City of Joplin v. Jasper County*, 161 S.W.2d 411, 413 (Mo. 1942) (a justiciable controversy must be "a case admitting of specific relief by way of a decree or judgment conclusive in character and determinative of the issues involved."); *Ferguson Police Officers Ass'n v. City of Ferguson*, 670 S.W.2d 921, 924 (Mo. App. E.D. 1984) ("The plaintiff must present a case in which specific relief can be given in a decision which will be res judicata as to the issues presented."). A "presently-existing controversy," as the words imply, requires only that the controversy exist now, as opposed to one that may arise in the future. The Board's tag that the court must resolve *prospective* rights incorrectly implies that courts may resolve controversies over rights that may come into fruition in the future. As *Missouri Soybean* held, courts may not do so as they would not be ripe. *Missouri Soybean*, 102 S.W.3d at 26-29.

To the contrary, the trial court was presented with a presently existing controversy. UPCO did not expressly or impliedly limit its request for declaratory relief to a construction of the law as it existed when the Cease and Desist Warning Letter was issued. As stated in paragraph 29 of UPCO's Petition:

> The controversy presently exists between this Plaintiff and the Defendant as to whether Plaintiff is required to comply with Defendant's licensure and regulatory requirements as a licensed pharmacy and to have a licensed pharmacist on duty when sales of federal veterinary legend drugs to consumers take place.

L.F. 14. It was clearly seeking a declaration of its *existing* rights and obligations – not those only at the time the Cease and Desist Warning Letter was issued.

In addition, in its prayer for relief, UPCO asked the court to "declare the Board of Pharmacy's Rules demanding Plaintiff comply with Defendant's licensure and regulatory requirements as a licensed pharmacy and to have a licensed pharmacist on duty when sales of federal veterinary legend drugs to consumers take place unlawful and void." L.F. 14. Again, the requested relief is not limited to the pre-2001 version of Chapter 338.

Indeed, the controversy over whether Chapter 338 authorizes the Board to regulate the sale by companies such as UPCO of federal veterinary legend drugs to consumers pursuant to a veterinary prescription did not end with the 2001

amendments to Chapter 338, as the Board suggests. Those amendments did not clear up the question of whether Chapter 338 was intended to grant the Board of Pharmacy jurisdiction over such sales. *See* Point II.B.4, *supra*. Like the pre-existing version of Chapter 338, the 2001 amended version of Chapter 338 does not expressly or impliedly state that an entity selling veterinary prescription drugs must have a pharmacy license or employ a pharmacist. Nothing in either the current or pre-2001 version evinces any legislative intent to extend the Board's power to include regulation of the sale of veterinary drugs. *See* A8, A11, A12.

For these reasons, a presently-existing controversy existed for the trial court to resolve, which it did.

a. The Trial Court Construed Chapter 338, as Amended in 2001

As evident from the plain and express language of the judgment, the trial court did, in fact, construe the *current* version of Chapter 338. In its judgment, the trial court stated: "Defendant further asserts that the revisions of Sec. 338.210 RSMo, resulting from the 2001 amendments thereto serve to clear up any confusion as to the conduct of Plaintiff . . . ." L.F. 219. The court continued: "*From its review of the provisions of Chapter 338 RSMo.*, this Court fails to discern any express legislative intent to extend the powers of the Defendant to encompass the regulation of drugs" for non-humans. *Id.* (emphasis added). This must be construed as referring to the

current provisions of Chapter 338, there being no language whatsoever to the contrary. *See Joseph Schnaider Brewing Co. v. Niederweiser,* 28 Mo. App. 233, 1887 WL 1723 (Mo. App. E.D. 1887) (trial court is presumed to have correctly applied the law); *State ex rel. Sch. Dist. of City of Independence v. Jones*, 653 S.W.2d 178, 191 (Mo. banc 1983) (trial court's judgment "is presumed valid"); *Von Seggern v. 310 West 49th St., Inc.*, 631 S.W.2d 877, 881 (Mo. App. W.D. 1982) (trial court's judgment is presumed correct "and is not to be reversed except on a firm belief that it is erroneous.").

The correctness of this interpretation is bolstered by the very next sentence of the court's judgment where it continued: *"Likewise*, the *existing* provisions of 4 C.S.R. 220-2.010 et seq. appear to authorize only specific regulation of pharmacists and pharmacies as classically defined by Secs. 338.010 and 338.210." L.F. 219 (emphasis added). This language shows beyond question that the trial court was properly considering the *current* state of the law, rather than the prior version of Chapter 338.

The fact that the trial court was construing the current version of Chapter 338 is further evidenced by the fact that the parties extensively argued the effect of the 2001 amendment both in their briefs (L.F. 37, 169) and in oral argument. Indeed, at oral argument, counsel for the Board characterized the issue presented as being the construction of the *current* law: "They are wanting you to declare what they can do

today, which means – The current statute is what matters. . . ." Tr. 8. The court responded: "I don't disagree with you. . . ." *Id.* The trial court's agreement with the Board's characterization of the issue conclusively establishes that the trial court was correctly focused on declaring UPCO's obligations under the *current* statute.

Moreover, when the trial court, in effect, asked counsel for UPCO whether the amended statute rendered UPCO's claims moot, counsel made it clear that the parties disagreed over the interpretation of the *current* law and therefore the court's construction of that law was absolutely at issue:

> THE COURT: Let me interrupt you. Hasn't the legislature done that [extend the Pharmacy Practices Act to require companies such as UPCO to obtain a pharmacy license] by the new 338.210, or are you disagreeing?
>
> * * *
>
> MR. BOULWARE: . . . My point, Judge, is there is nothing in that statute that makes any application to animals whatsoever. And you pointed this out yourself earlier. It refers to patients . . . .
>
> My point is this: If we are going to require UPCO to become Osco, it needs to be clearly legislated. Now, Mr. Hylton, and I admire his fervor saying it's clear. It's not clear. And furthermore, there is no Court in the state of Missouri that has ever held that statute that they are referring to

> applies to animals, ever. And for good reason, it doesn't. It makes no sense. I think you can go back to the previous statute that you are talking to and I think it also made clear it didn't apply. There is no reason to believe that it is.

Tr. 20-21.

Still further, in closing argument, UPCO's counsel presented the following question to the court to resolve: "What Mr. Hylton just told you is even under the old statute, 338.210, it was also clear under that statute that it applied to animals. *If we can agree that if the old statute didn't apply to the animals, what is it in the new statute that would really make that clear*?" Tr. 37 (emphasis added).

The foregoing clearly shows that the trial court was well aware that its task in this case was to construe the *current* version of Chapter 338 and it did so.

The Board's erroneous belief that the court was declaring UPCO's obligations under the law in effect at the time the Cease and Desist Warning Letter was issued is primarily based on a statement in the court's judgment about retrospective application of the law: "This Court does not find persuasive the argument that as an after-the-fact change in the law . . . might appear to justify the position the Defendant now takes. . ." The Board misconstrues the court's statement. The court was merely expressing its disagreement with the Board's argument that an after-the-fact legislative confirmation of its position somehow justifies its prior unauthorized acts.

Specifically, the Board promulgated a rule without following the required rule-making procedures. It then sought to enforce that unauthorized rule. The legislature later expanded the definition of "pharmacy," which, the Board contends, confirms that veterinary drugs have always been within the scope of the Pharmacy Practices Act. In effect, the Board attempted to justify its enforcement of an unauthorized rule by arguing that the amended law *now* supports its earlier actions. The trial court was disturbed, and justifiably so, by the fact that the Board sought "early enforcement of what [according to the Board's perspective] presently exists at 338.210." Tr. 30. In other words, the trial court's statement about retrospective application of the law was not meant to suggest that the court was construing the law in effect at the time the Cease and Desist Warning Letter was issued but rather its displeasure with the Board's premature enforcement of the new Chapter 338 (assuming, without deciding, that the amended Chapter 338 did, indeed, make it clear that it applies to veterinary drugs as the Board contends).

The Board also bases its argument that the trial court was construing the prior version of Chapter 338 on two statements made at oral argument: (1) "What is to prevent the attorney general, should your client obtain the relief that he is seeking under the petition from beginning day one and commencing under their interpretation of 338.210 issuing another Cease and Desist Order . . . ." (Tr. 25); and (2) "My concern is whether your client were to prevail on this petition or not, I am uncertain

as to the status he would be placed in respecting attempts by the State of Missouri to enforce the existing 338.210." (Tr. 26-27). The trial court's queries at oral argument certainly do not establish that the trial court was not focused on the proper issue at the time it subsequently entered its judgment. Indeed, the plain language of the court's ultimate judgment reflects that it did, in fact, construe the *current* version of Chapter 338.

Again, as a matter of law, it must be presumed that the trial court's judgment reflected its ruling with regard to Chapter 338, as amended. *See Joseph Schnaider Brewing Co.*, 1887 WL 1723; *State ex rel. Sch. Dist. of City of Independence*, 653 S.W.2d at 191; *Von Seggern*, 631 S.W.2d at 881. The burden is on the Board to show that the trial court considered the wrong issue. *See State ex rel. Sch. Dist. of City of Independence*, 653 S.W.2d at 191 (appellant bears the burden of showing incorrectness of judgment). The Board failed to rebut that presumption. *See Von Seggern*, 631 S.W.2d at 881 (judgment "is not to be reversed except on a firm belief that it is erroneous."). To the contrary, a plain reading of the court's judgment, as well as the transcript of the hearing, reveals that the trial court properly construed UPCO's rights under the current version of Chapter 338. Because the trial court construed Chapter 338, as amended, it resolved a presently existing controversy concerning UPCO's rights and obligations. Accordingly, its declaratory judgment was proper and must be affirmed.

2. UPCO Satisfied the Remaining Elements of a Declaratory Judgment Action

Although not challenged by the Board, for the record, UPCO submits that the other required elements for a declaratory judgment action are satisfied. UPCO has a "legally protected interest" at stake that is "subject to immediate or prospective consequential relief." *Missouri Soybean*, 102 S.W.3d at 25. The Board's Cease and Desist Letter jeopardizes UPCO's right to engage in a business that has engaged in for at least 10 years with the Board's knowledge and approval. It also threatened UPCO with criminal prosecution of a felony under RSMo § 338.195 (2000) (A10). *See* L.F. 124.

The controversy presented in this petition is also ripe for judicial determination. *See Missouri Soybean*, 102 S.W.3d at 25. A controversy is ripe if there is "sufficient immediacy and reality" as opposed to merely a "probability that an event will occur." *Id.* at 26 (citations omitted). Again, the Board served its Cease and Desist Warning Letter on UPCO, stating that it had determined that UPCO was engaged in the unlicensed practice of pharmacy in violation of sections 338.010 and 338.220. L.F. 123-25. The letter gave UPCO just ten days to respond, and also threatened criminal prosecution if it failed to immediately stop the unlicensed practice of pharmacy. *See* L.F. 124-25. The Warning Letter was not an idle threat. Indeed, after sending a similar Cease and Desist Warning Letter to Chariton Vet Supply, the Board filed a

civil action against Chariton seeking declaratory relief. L.F. 75. This stands in stark contrast to *Missouri Soybean*, where the appellants merely speculated that regulations might be promulgated that would harm them. *Missouri Soybean*, 102 S.W.3d at 28-29.

And, no adequate remedy at law exists. *Missouri Soybean*, 102 S.W.3d at 25. Because UPCO does not have a pharmacy license, the administrative procedures under the Pharmacy Practices Act are unavailable to it. UPCO's only recourse is a declaratory judgment action. And, again, UPCO faces felony prosecution pursuant to § 338.195. As the appellate court stated, this threat "left little for the respondent to do other than to file for declaratory relief."

For these reasons, declaratory judgment was proper and should be affirmed.

IV. CONCLUSION

Respondent United Pharmacal Company of Missouri, Inc. respectfully requests this Court to affirm the judgment of the trial court in all respects, and for an award of its attorneys' fees and expenses pursuant to RSMo § 536.050.3.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I did on this 1st day of October, 2004, cause a copy of the foregoing the **RESPONDENT'S SUBSTITUTE BRIEF** to be sent via Federal Express, next business day delivery, postage prepaid, with a copy on floppy disk, to:

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ATTORNEY FOR DEFENDANT-APPELLANT
MISSOURI BOARD OF PHARMACY

_____
ATTORNEY FOR RESPONDENT

RULE 84.06(C) AND (G) CERTIFICATES

I hereby certify that **RESPONDENT'S SUBSTITUTE BRIEF** includes the information required by Rule 55.03, and that the brief complies with the limitations contained in Rule 84.06(b). Respondent's Brief consists of 14,682 words, exclusive of the cover, certificate of service, certificate required by Rule 84.06(g), signature block and appendix, as determined by the word count of the Microsoft Word word-processing system.

I hereby certify that the floppy disk submitted by Respondent in this matter has been scanned for viruses and that it is virus free.

BY: _____
ATTORNEY FOR RESPONDENT

APPENDIX

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